



FH
[REDACTED]

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/156194

PRELIMINARY RECITALS

Pursuant to a petition filed March 17, 2014, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on May 29, 2014, at Kenosha, Wisconsin.

The issue for determination is whether the Department of Health Services (DHS) correctly denied Petitioner's request for authorization of Namenda.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: OIG by letter

Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

Mayumi M. Ishii
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES # [REDACTED]) is a resident of Kenosha County.

2. On January 3, 2014, Aurora Pharmacy, submitted on behalf the Petitioner a request for prior authorization of a prescription for Namenda to treat Nystagmus. (Exhibit 3, pg. 8)
- 3.
4. Nystagmus is a condition in which a person's eyes move involuntarily in a rapid and repeated up and down or side to side motion. (Testimony of Petitioner's father; Exhibit 3, pgs. 3 and 45)
5. On February 3, 2013, the Department of Health Services (DHS) sent Petitioner a notice advising her that the request for authorization for Namenda was denied. (Exhibit 3, pgs. 52-55)
6. On February 3, 2013, DHS sent notice of the same to Aurora Pharmacy. (Exhibit 3, pgs. 56 and 57)
7. The Petitioner's father, on behalf of Petitioner, filed a request for fair hearing that was received by the Division of Hearings and Appeals on March 17, 2014. (Exhibit 1)
8. Petitioner is 18 years old. (Exhibit 1, pg. 3; Exhibit 3, pg. 8)
9. Petitioner does not have a diagnosis of Alzheimer's dementia. (Testimony of Petitioner's father)

DISCUSSION

The Department of Health Services sometimes requires prior authorization to:

1. Safeguard against unnecessary or inappropriate care and services;
2. Safeguard against excess payments;
3. Assess the quality and timeliness of services;
4. Determine if less expensive alternative care, services or supplies are usable;
5. Promote the most effective and appropriate use of available services and facilities; and
6. Curtail misutilization practices of providers and recipients.

Wis. Admin. Code § DHS107.02(3)(b)

In determining whether to approve or disapprove a request for prior authorization, the department shall consider:

1. The medical necessity of the service;
- 2. The appropriateness of the service;**
3. The cost of the service;
4. The frequency of furnishing the service;
5. The quality and timeliness of the service;
6. The extent to which less expensive alternative services are available;
- 7. The effective and appropriate use of available services;**
8. The misutilization practices of providers and recipients;
9. The limitations imposed by pertinent federal or state statutes, rules, regulations or interpretations, including Medicare, or private insurance guidelines;
10. The need to ensure that there is closer professional scrutiny for care which is of unacceptable quality;
11. The flagrant or continuing disregard of established state and federal policies, standards, fees or procedures; and
- 12. The professional acceptability of unproven or experimental care, as determined by consultants to the department.**

Emphasis added. Wis. Admin. Code §DHS107.02(3)(e)

“Medically necessary” means a medical assistance service under ch. DHS 107 that is:

- (a) Required to prevent, identify or treat a recipient's illness, injury or disability; and
- (b) Meets the following standards:
 1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
 2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
 3. Is appropriate with regard to generally accepted standards of medical practice;
 4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
 - 5. Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;**
 6. Is not duplicative with respect to other services being provided to the recipient;
 7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
 8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and
 - 9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.**

Emphasis added. Wis. Adm. Code. §DHS 101.03(96m)

Petitioner has the burden to prove, by a preponderance of the credible evidence that the requested level of therapy meets the approval criteria.

Prescription drugs and drug products are a covered Medicaid service when properly prescribed. Wis. Admin. Code §DHS 107.10(1) Prior Authorization for prescription drugs is required for, “drugs the department has determined entail substantial cost or utilization problems for the MA program. These drugs shall be noted in the Wisconsin Medicaid drug index...” Wis. Admin. Code §DHS 107.10(2)(d)

Namenda is an N-methyl-D-aspartate receptor antagonist in the Alzheimer's agents drug class. Namenda is used in the treatment of Alzheimer's disease and dementia-related disorders. (*Note:* There are no adequate and well-controlled trials documenting the safety and efficacy of Namenda in any illness occurring in children.)

Namenda is a preferred drug; however, PA [prior authorization] is required for Namenda for members who are 44 years of age or younger. For members 45 years of age or older, PA is not required for Namenda.

Topic 15037 of the On-line Provider Handbook; Exhibit 2, pgs. 7 and 21

The On-line Provider Handbook can be found at:

<https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx>

The Petitioner is 18 years old, as such, prior authorization is required for coverage of Namenda. However, the Petitioner does not have Alzheimer's dementia.

The use of Namenda to treat Petitioner's Nystagmus is considered an off-label use; that is to say, that Namenda has not been FDA approved to treat Nystagmus. Information concerning FDA approved uses of Namenda can be found at:

www.accessdata.fda.gov

DHS's medical consultant attached a portion of that information in Exhibit 2, pgs. 119-143. According to that information, Namenda is approved for moderate to severe Alzheimer's dementia. (Exhibit 2, pg. 119) The FDA information further indicates that the safety and effectiveness of Namenda for pediatric patients has not been established. (Exhibit 3, pg. 122)

Neither Petitioner's physician, nor Aurora Pharmacy has provided any reliable studies showing that Namenda may be used safely and effectively to treat Nystagmus in pediatric/young patients. Aurora Pharmacy submitted two articles from medical journals. The first, entitled "Treatment of Nystagmus", does not make clear the number of patients studied or their ages. (Exhibit 3, pgs. 16-28) The second article, entitled "The Pharmacological Treatment of Acquired Nystagmus" does not discuss the use of Namenda and states:

The potential advantages of pharmacological treatment over other procedures are considerable. Drugs are reversible and do not require access to specialist services. However, the available drugs have not yet been properly evaluated and there are relatively few randomized controlled trials and level 1 evidence. Indeed, much neuro-ophthalmological practice relies upon grade C and D recommendations – expert opinion, case reports and series – often without reliable measurements of the involuntary ocular movements or their visual consequences. A handful of randomized controlled trials have been published recently. However, they had only small numbers of participants and not all improved with the treatment. The follow-up duration was invariably short, precluding firm conclusions about treatment acceptability and safety. Moreover, the methods of quantifying nystagmus and its visual consequences are not standardized across studies. Thus, these isolated studies have debatable validity.

Emphasis added. (Exhibit 3, pg. 45)

Consequently, there is insufficient evidence to show that use of Namenda is appropriate under Wis. Admin. Code §DHS 107.02(3)(e) 2, 7 and 12, above.

In addition, the requested use of Namenda cannot be deemed "medically necessary" as defined by Wis. Admin. Code §DHS 101.03(96m)(b) 5 and 9, because there is insufficient clinical evidence to establish that Namenda has been proven to be safe and useful in the treatment of Nystagmus or is otherwise NOT experimental in nature.

Based upon the foregoing it is found that Petitioner's request for authorization of Namenda to treat Nystagmus does not meet approval criteria.

The Petitioner's father testified that it is unfair to deny his daughter coverage for Namenda because it has been effective in treating his daughter's Nystagmus and that it has a significant advantage over other medications because it is not overly sedating. However, this is an equitable argument and administrative law judges do not have the authority to consider such arguments.

Petitioner should note that although the current prior authorization request must be denied, there is nothing precluding her physician from engaging in a peer to peer review of the medication. *See Wis. Admin. Code DHS §107.035 Definition and Identification of Experimental Services.*

CONCLUSIONS OF LAW

DHS correctly denied the Petitioner's request for authorization of Namenda.

THEREFORE, it is

ORDERED

That the petition is dismissed.

REQUEST FOR A REHEARING

This is a final administrative decision. If you think this decision is based on a serious mistake in the facts or the law, you may request a rehearing. You may also ask for a rehearing if you have found new evidence which would change the decision. Your request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and tell why you did not have it at your first hearing. If you do not explain these things, your request will have to be denied.

To ask for a rehearing, send a written request to the Division of Hearings and Appeals, P.O. Box 7875, Madison, WI 53707-7875. Send a copy of your request to the other people named in this decision as "PARTIES IN INTEREST." Your request for a rehearing must be received no later than 20 days after the date of the decision. Late requests cannot be granted.

The process for asking for a rehearing is in Wis. Stat. § 227.49. A copy of the statutes can be found at your local library or courthouse.

APPEAL TO COURT

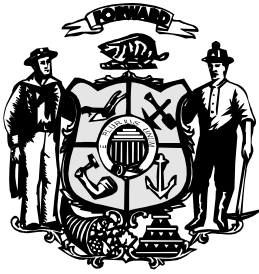
You may also appeal this decision to Circuit Court in the county where you live. Appeals must be served and filed with the appropriate court no more than 30 days after the date of this hearing decision (or 30 days after a denial of rehearing, if you ask for one).

For purposes of appeal to circuit court, the Respondent in this matter is the Department of Health Services. After filing the appeal with the appropriate court, it must be served on the Secretary of that Department, either personally or by certified mail. The address of the Department is: 1 West Wilson Street, Room 651, Madison, Wisconsin 53703. A copy should also be sent to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400.

The appeal must also be served on the other "PARTIES IN INTEREST" named in this decision. The process for appeals to the Circuit Court is in Wis. Stat. §§ 227.52 and 227.53.

Given under my hand at the City of Milwaukee,
Wisconsin, this 3rd day of July, 2014.

\sMayumi M. Ishii
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

Brian Hayes, Administrator
Suite 201
5005 University Avenue
Madison, WI 53705-5400

Telephone: (608) 266-3096
FAX: (608) 264-9885
email: DHAmail@wisconsin.gov
Internet: <http://dha.state.wi.us>

The preceding decision was sent to the following parties on July 3, 2014.

Division of Health Care Access and Accountability